

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2055846	<b>(X3) Date Survey Completed</b>  02/25/2025
<b>Name of Provider or Supplier</b>  Baton Rouge Clinic Industriplex	<b>Street Address, City, State</b>  12351 Industriplex Blvd, Baton Rouge, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed at Baton Rouge Clinic Industriplex, INC, CLIA ID 19D2055846, on February 25, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written quality control procedure for visual inspections of blood culture bottles and media. 2. In interview on February 25, 2025 at 2:00 pm, Technical Consultant 3 confirmed the laboratory did not have a written procedure for visual inspections of blood culture bottles and media.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for</p>

the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to have complete precision and reference range studies for Complete Blood Count (CBC) testing. Findings: 1. Observation by surveyor during the laboratory tour on February 25, 2025 at 10:01 am revealed the laboratory utilizes a Sysmex XN-330 for CBC testing. 2. Review of the laboratory's "Method Performance Verification/Validation" form for the Sysmex XN 330, in use September 19, 2023, revealed the following: a) "Precision-must demonstrate within run, (simple precision), between run, and operator variance. Within run: manufacturer will run a single specimen in replicate 10; minimum 10 runs for intra-assay precision." b) "Reference ranges: minimum of 10 samples will be tested to span the analytical range of testing, if able to obtain 10 'normal' pediatric samples. Acceptance Criteria/Acceptable Failure Rate: Will utilize current reference ranges or published data to verify reference intervals. If able to obtain 10 normal patients.. No more than one outlier. If no more than one outlier, the reference interval is verified. Correction Action for Failures: If unable to obtain enough normal pediatric samples, reference intervals will be verified by obtaining an acceptable method comparison which allows the RI to transfer to the instrument since there has been no change in patient demographic." 3. Review of the laboratory's performance specification studies revealed the laboratory did not include the following: Precision: raw data for within-run studies and documentation of operator variance Reference range: Clinical reference or studies to support the reference range in use 4. In interview on February 25, 2025 at 1:55 pm, Technical Consultant 3, confirmed the laboratory did not include the identified items with their performance specification studies.

**D5477**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(4)(g)

(e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's policies, manufacturers' package inserts, and interview with personnel, the laboratory failed to document the visual inspection of media and blood culture bottles per manufacturers' requirements. Findings: 1. Observation by surveyor during the laboratory tour on February 25, 2025 at 10:01 am revealed the laboratory utilizes the following media and blood culture bottles for collection only: BD BBL TSA II 5% sheep blood media BD BBL COL CN /MAC II media BacT/ALERT FN Plus BacT/ALERT FA Plus BacT/ALERT PF Plus 2. Review of the BD BBL media package insert revealed "Examine plates as described under 'Product Deterioration.' Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking, or other signs of deterioration." 3. Review of the BacT/ALERT blood culture bottles package insert

	<p>revealed to perform an examination of bottles for evidence of damage or deterioration (discoloration). "Do not use a bottle which contains medium exhibiting turbidity, a yellow sensor, or excess gas pressure, these are signs of possible contamination." 4. Review of the laboratory's policies revealed the laboratory did not have a policy related to visual inspections of media and blood culture bottles. 5. In interview on February 25, 2025 at 2:00 pm, Technical Consultant 3 stated the laboratory receives media and blood culture bottles from the main clinic. Technical Consultant 3 confirmed the laboratory does not document visual inspections of the media and blood culture bottles received.</p>
<b>D6013</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.</p>
<b>D6014</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5477.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were maintained. Refer to D6051.</p>
<b>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p>

	<p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5477.</p>
<p><b>D6040</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(2)</p> <p>(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance verification studies, and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421.</p>
<p><b>D6051</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel competency records, proficiency testing records, and interview with personnel, the Technical Consultants failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for three (3) of five (5) testing personnel was performed annually in 2023 and 2024. Findings: 1. Review of the laboratory's personnel competency records and proficiency testing records for 2023 and 2024 revealed the following personnel did not have the assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples performed: 2023: Testing Personnel 4 2024: Testing</p>

Personnel 2 and Testing Personnel 3 2. In interview on February 25, 2025 at 2:00 pm , Technical Consultant 1 confirmed the identified three (3) personnel did not have an assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples performed.